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APPLICATION N	D. F	TILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,787		06/18/2002	Peter Neubauer	10806-193	9630
24256	7590	09/09/2005		EXAMINER	
	RE & SH	•	MONDESI, ROBERT B		
	MED CEN			ART UNIT	PAPER NUMBER
	ATI, OH		1653		

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)					
	10/070,787	NEUBAUER ET AL.					
Office Action Summary	Examiner	Art Unit					
	Robert B. Mondesi	1653					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPI THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a re  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the maili earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a reply be to ply within the statutory minimum of thirty (30) do will apply and will expire SIX (6) MONTHS frow the cause the application to become ABANDON	imely filed  ays will be considered timely.  the mailing date of this communication.  ED (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on 14	Responsive to communication(s) filed on 14 March 2005.						
· <u> </u>	,—						
•	Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
closed in accordance with the practice under	Ex parte Quayle, 1955 C.D. 11,	133 O.G. 213.					
Disposition of Claims							
5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) <u>1-20</u> is/are rejected. 7) ☐ Claim(s) is/are objected to.	4a) Of the above claim(s) is/are withdrawn from consideration.  Claim(s) is/are allowed.  Claim(s) <u>1-20</u> is/are rejected.						
Application Papers							
9) The specification is objected to by the Examination The drawing(s) filed on is/are: a) and according an according and according to the Replacement drawing sheet(s) including the corresponding to the specific path or declaration is objected to by the Examination is objected to be accordingly in the Examination	ccepted or b) objected to by the education of the drawing(s) be held in abeyance. So ction is required if the drawing(s) is consistent of the drawing(s) is consistent or the drawing(s) is consistent or the drawing(s) is consistent or the drawing(s).	ee 37 CFR 1.85(a). bjected to. See 37 CFR 1.121(d).					
Priority under 35 U.S.C. § 119		-					
a) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documer 2. Certified copies of the priority documer 3. Copies of the certified copies of the priority application from the International Bures* See the attached detailed Office action for a list	nts have been received. nts have been received in Applica ority documents have been recei au (PCT Rule 17.2(a)).	ntion No ved in this National Stage					
Attachment(s)	Λ Π I=	n: (PTO 413)					
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date</li> </ol>	4) Interview Summa Paper No(s)/Mail  5) Notice of Informal 6) Other:						

U.S. Patent and Trademark Office PTOL-326 (Rev. 1-04)

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#### **DETAILED ACTION**

This Office action is in response to the amendment filed March 14, 2005. Claims

1- 20 are presently pending and under examination.

## **Priority**

The current application filed on June 18, 2002 is a 371 of PCT/EP00/08984 filed on September 13, 2000, which in turn claims priority to a foreign application, GERMANY 19943919.2 filed on September 14, 1999. A certified copy of foreign document GERMANY 19943919.2 has been provided.

# Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn.

# New Objection(s) and Rejection(s)

#### **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,680181.

Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant applications **claim 1** is directed to a method of for increasing the yield of recombinant protein in a microbial fermentation process, wherein the concentration of a carbon/ energy source in the culture of microbial fermentation process for producing recombinant protein is oscillatingly reduced or increased in cycles and wherein the maximum duration of each cycle is 4 minutes.

Claim 1 of US Patent 6,680181 are directed to Method for the production of recombinant peptide by fed-batch cultivation of a microorganism in a bioreactor containing a medium comprising organic carbon source, nitrogen source and mineral salts, wherein the cultivation is carried out by the addition of the organic carbon source in oscillation feed and/or by oscillation variation of stirring speed, without exhaustion of the organo carbon source during the oscillation period, wherein the oscillation has a wave period of from about 1 to about 30 minutes, wherein the microorganism is a biological host selected from the group consisting of bacteria, yeast and animal cell, and wherein the cultivation conditions remain aerobic.

Claim 1 of the instant application does not state that microorganism being cultured in the method of recombinant production is selected from the group consisting of bacteria, yeast and animal cell and that the oscillation cycle is 4 minutes; however it would have been obvious to use a microorganism as a host for the fermentation

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process selected form a group consisting of bacteria, yeast, and animal cells and also it is apparent that a 4 minute cycle falls within the scope of a wave period that is form about 1 to about 30 minutes.

Claims 2-20 of the present application and claims 2-27 of US Patent 6,680,181 are optimization steps of the same method.

### Conclusion

No claims are allowed

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi
Patent Examiner
Group 1653

JON WEBER
SUPERVISORY PATENT EXAMINER